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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/016,159	01/30/1998	JONG Y. LEE	07004-002004	6621

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/016,159	LEE, JONG Y.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5 and 10-14* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 5, 11, 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions:

1a. Applicant's election without traverse of the invention of Group II (claims 3, 5 and 11-14) filed on 02 March 2004 is acknowledged.

Status of Claims:

1b. Claims 1-2, 4 and 6-9 have been cancelled. Claims 3, 5, 10, 11-14 are pending. Claim 10 is withdrawn from consideration, by the Examiner, as it is drawn to non-elected invention. Thus claims 3, 5, 11-14 are under consideration.

2. The following previous rejection are withdrawn in light of Applicants amendments filed on 03/10/04:

2a. All of the rejections made against claims 3, 5, 11-14 are withdrawn.

New Rejections:

Claim Rejections - 35 U.S.C. § 101:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claims 3 and 13 are directed to non-statutory subject matter. Claims 3 and 11 recite "A polypeptide.....", which encompasses the polypeptide as it occurs in nature. However, since Applicants do not intend to claim a naturally occurring product, it is suggested to recite "an isolated...", before polypeptide to show the hand of man. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 3, 5, 11, 12-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 is drawn to "a polypeptide consisting essentially of amino acid 25 to amino acid 250 of full length human erythropoietin receptor protein", and claims 11 and 13 are drawn to " a polypeptide ...., wherein the human erythropietin receptor extracellular domain is expressed from a region of full length human erythropoietin receptor DNA defined on the 5' end by a forward primer SEQ ID NO:1 and defined at the 3' by a reverse primer SEQ ID NO:2". The specification discloses the structure of the human erythropoietin polypeptide as set forth in SEQ IID NO:5, said polypeptide consisting of 508 amino acid residues and encoded by the nucleic acid of SEQ ID NO: 4. However, SEQ ID NO:5 is not recited in the instant claims and therefore, the claims encompass polypeptides which are not described by the Applicants. With the exception of the polypeptide of SEQ ID NO:5, encoded by the nucleic acid as s et forth in SEQ ID NO:4, one of one of ordinary skill in the art would not be able to visualize the structures of the polypeptide encompassed by instant claims 3, 11 and 13. The specification does not teach structural characteristics of all the claimed polypeptides. Therefore, the description of one polypeptide (SEQ ID NO: 5) is not adequate written description of an entire genus of functionally equivalent polypeptides. To provide adequate written

description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation amino acid residues or the 5' and 3' sequences encoding said polypeptide. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

Therefore, only the isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5, encoded by SEQ ID NO:4, but not the full breadth of the claims

meet the written description provision of 35 U.S.C. §112, first paragraph. Reciting the appropriate SEQ ID: NOs in the claims would obviate this rejection.

5. Claims 3, 5, 11, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 3 and 11 recite the phrase "..... *consisting essentially* ....." which renders the claims indefinite because it is unclear whether the claimed polypeptide consists only of the amino acid residues 25-250 of full length human erythropoietin receptor or whether said polypeptide also consists of other components besides these residues. Appropriate correction is required.

5b. Claim 13 recites "...a polypeptide consisting of a *free* human erythropietin receptor extracellular domain...", which renders the claim unclear, because it is unclear what the claimed invention is free from? The metes and bounds of the claim cannot be ascertained.

Claims, 5, 12 and 14 are rejected insofar as they depend on claims 3 and 13 for the limitations set forth directly above.

Claim Rejections - 35 U.S.C. § 102 (b):

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 3, 5, 11, 12-14 are rejected under 35 U.S.C § 102(b) as being anticipated by Jones et al (published July 1990).

Jones et al disclose an isolated nucleic acid encoding human erythropoietin receptor polypeptide and the encoded polypeptide, (see figure 1 A and 1B). The polypeptide disclosed by Jones et al consists of 508 amino acid residues, and comprises amino acid residues 25 to 250 of the full length human erythropoietin receptor. The Jones et al reference also discloses a cell proliferation assay in which the effect of EPO on a cell line expressing the human erythropoietin receptor were measured, after growing said cells on a 96-well microtiter plate, (see page 32).

Because of the ambiguity of the recitation "consisting essentially of" in claims 3 and 11, the polypeptide taught by Jones et al reads on the claimed polypeptide, since the claimed polypeptide could consist more than the recited 25-250 amino acid residues. With respect to claim 5, the proliferation assay disclosed by Jones et al meets all the limitations recited in this claim. With respect to claim 13, SEQ ID Nos: 1 and 2 are contained within the nucleic acid disclosed by Jones et al, therefore, the claimed polypeptide could be expressed from the Jones et al nucleic acid. With respect to claims 12 and 14, the Jones et al reference discloses the nucleic acid encoding the human erythropoietin receptor, (see figure 1A). Therefore, Jones et al anticipates instant claims 3, 5, 11-14, in the absence of any evidence to the contrary.

Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
12 May 2005

Prema Mertz
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PRIMARY EXAMINER